UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,750	09/05/2003	Johnson E. Goode	P0011367.00	9063

27581 7590 11/29/2007

MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No.	Applicant(s)	
	10/656,750	GOODE ET AL.	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The phrase "which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a)" should not be used in the declaration and should be replaced with "which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56".

Drawings

2. The drawings were received on September 17 2007. These drawings are acceptable. However, it is noted that the features in Figure 3 in the replacement sheet received September 17 2007 is not as clear as the features in Figure 3 in the replacement sheet received March 9 2007. Therefore, it is requested that a replacement sheet be submitted which shows Figure 3 as filed on March 9 2007.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the

description: 157 (line 29 of page 8). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification fails to disclose what is meant by "the outer layer along the first portion of the shaft being of uniform thickness" and "the outer layer along the second portion of the shaft forms a first lumen portion" as applicant has not clearly described where the first portion and the second portion of the shaft are relative to the various portions of the shaft. It appears, however, that the braided non-deflectable portion (108) which extends from a proximal end (110) to a distal end (112) refers to the first portion of the shaft and the steerable portion (114) which extends from a proximal end (116) to a distal end (118) refers to the second portion of the shaft. Therefore, the first portion

and the second portion of the shaft need to be clearly defined as to their relationship with the other portions of the shaft. The specification also fails to disclose a shaft including a first portion and a second portion and further fails to disclose a proximal shaft end, a first portion distal end, a second portion proximal end, and a second portion distal end. It is suggested that the first and second portions of the shaft be defined as a first shaft portion and a second shaft portion in the specification and in the appropriate claims to distinguish the first portion of the shaft from the first portion of the inner wall (155). Then, the shaft can be defined in terms of a first shaft portion having a first shaft portion distal end and a first shaft portion proximal end and a second shaft portion having a second shaft portion distal end and a second shaft portion proximal end. The language used to define the first portion and the second portion of the shaft in the claims should have proper antecedent basis in the specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 11, 16, 19, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Wardle (U.S. Patent No. 4,748,969).

Wardle discloses a medical therapy delivery device having a shaft with a first portion (14) and a second portion (12). As shown in Figure 4, a deflectable tip (48)

extends distally from the second portion and has a tapered portion and a tip lumen (shown at 58). The device also includes a manipulator wire (40) that extends through the shaft and a thru lumen tubing (32) having a thru lumen. In Figures 2 and 5, the outer layer of the shaft forms a single shaft lumen having a first lumen portion (shown at 28 in Figure 2 and at 6 in Figure 5) positioned about the thru lumen tubing and a second lumen portion (shown above the portion shown at 28 in Figure 2 and above the portion shown at 6 in Figure 5) having a first side wall, a second side wall, and a bottom side wall which position the manipulator wire within the second lumen portion. The second lumen portion is offset from and in fluid communication with the first lumen portion. As to claim 11, as shown in Figure 4, an anchoring device or band (72) is positioned along a distal end of the second portion and is fixedly engaged with the manipulator wire (40). Also shown is the manipulator wire (40) that extends through the transition lumen of the transition tubing (30). As to claim 16, Wardle discloses a portion (50) of the thru lumen tubing is capable of sliding within the shaft during deflection of the second portion of the shaft (lines 40-63 of column 7). As to claim 19, in Figure 5, Wardle shows the first and second flanges as claimed. As to claim 20, Figures 2 and 5 shows the thru lumen tubing (32), the first side wall, the second side wall, and the bottom side wall positioning the transition tubing (30) within the second lumen portion. As to claim 22, the first lumen portion is generally semi-circular in shape and the second lumen portion is generally rectangular in shape.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2, 3, 7, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle in view of Stewart et al (U.S. Patent No. 6,926,669).

Wardle discloses the invention substantially as claimed. Even though Wardle teaches in line 61 of column 5 to line 14 of column 6 that the outer layer (66) is formed of a polymer and contain a stainless steel braiding (67) to provide torsional stiffness to the shaft, Wardle is silent on the outer layer being specifically formed of polyether block amide and including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. Wardle is also silent on the thru lumen being formed polyether block amide having a durometer reading of 72D. In Figure 15, Stewart et al show the outer layer of a medical device having a first portion (22) made of a high durometer (such as 72D) polyether block amide with a stainless steel braiding and a second non-braided portion and teach that the braiding provided reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the outer layer and the thru lumen of Wardle with a polyether block amide as taught by Stewart et al as both Wardle and Stewart et al teach that it is well known to use polymer materials for medical devices and Stewart et al

teach the use of polymer materials such as polyether block amide. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to make the first portion of the outer layer of Wardle with a high durometer (such as 72D) polyether block amide with a stainless steel braiding as taught by Stewart et al as both Wardle and Stewart et al disclose devices having a deflectable second portion and Stewart et al teach that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Stewart et al teach that the second portion (30) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer reading of the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the thru lumen tubing being formed polyether block amide having a durometer reading of 72D in claim 7, Stewart et al do disclose polyether block amide as a suitable material for a medical device and the parameter of the durometer reading of the thru lumen tubing is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the transition tubing having a length of approximately one inch in claim 18, the parameters of length is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

9. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle in view of Hobot et al (Pub. No. US 2003/0109823).

Wardle discloses the invention substantially as claimed. However, Wardle is silent on the deflectable tip being formed of a radio opaque and echo-genic polyether block amide material loaded with jet milled tungsten carbide and having a durometer reading of 35D. Hobot et al disclose a medical device having a deflectable tip (24) made of a polyether block amide material loaded with jet milled tungsten carbide and having a durometer reading of 35D. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the deflectable tip of Wardle with from a radio opaque and echo-genic polymer material such as a polyether block amide material loaded with jet milled tungsten carbide and having a durometer reading of 35D as taught by Hobot et al as both Wardle and Hobot et al teach advancing a medical device in narrow vessels or cavities and Hobot et al teach that it is beneficial to have a tip that allow the distal end of the medical device to be seen by the user as it is advanced in the body.

10. Claims 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle.

Wardle discloses the invention substantially as claimed. Wardle discloses that the tip includes a distal opening and, in Figure 4, the distance between the outer wall and inner wall gradually decreases between the proximal end and the distal end of the tapered portion. However, Wardle does not disclose the thicknesses of the walls of the deflectable tip or the diameters of the various components of the medical device.

However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle in view of Truckai (U.S. Patent No. 5,397,304).

Wardle discloses the invention substantially as claimed. However, Wardle does not disclose the transition tubing being formed of a polyimide material having a durometer reading of 86D. In Figure 2, Truckai shows a steerable medical device having a polyimide transition tubing (58) through which a manipulator wire extends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the transition tubing of Wardle from a polyimide material as taught by Truckai as both Wardle and Truckai disclose steerable devices having a transition tubing through which a manipulator wire extends and Truckai teaches that it would be advantageous to make the transition tubing from polyimide to provide lateral and torsional stiffness to the deflectable tip. As to the limitation of the polyimide material having a durometer reading of 86D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

12. Claims 13-15, 17, 21, 23-26, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle in view of Ponzi (U.S. Patent No. 5,897,529).

Wardle discloses the invention substantially as claimed as discussed above. Even though Wardle discloses the medical device having a compressible member

through which the manipulator wire extends and the distal end of the compressible member fixedly engaged with the outer layer (lines 15-40, column 6), Wardle is silent on the specifics of the compressible member being positioned between the distal end of the transition tubing and the anchoring band and being free to move relative to the manipulator wire and the shaft during deflection of the second portion. In Figure 2, Ponzi shows a steerable medical device having a compressible member (44) through which a manipulator wire (42) extends. In lines 14-45 of column 6, Ponzi teaches that the compressible member is anchored at its proximal end and distal end thus allowing it to move freely relative to the manipulator wire and the shaft during defection. The wire preferably has a diameter ranging from about 0.006 to 0.010 inches. The inner diameter of the compressible member is preferably slightly larger than the diameter of the manipulator wire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to position the compressible member of Wardle between the distal end of the transition tubing and the anchoring band where the distal end of the compressible member is fixedly engaged with the outer layer so that the compressible member can move freely as taught by Ponzi as both Wardle and Ponzi disclose steerable devices having a compressible member through which a manipulator wire extends and Ponzi teaches that it would be advantageous to have a compressible member to provide flexibility to the deflectable portion of the steerable device. As the limitation of the diameters of the compressible members in claim 14, the parameter of diameters is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to

the limitation of the transition tubing having a stiffness greater than the compressible member in claim 17, it would be obvious to one having ordinary skill in the art at the time the invention was made that transition tubing of Wardle would be stiffer than the flexible compressible member of Ponzi as the compressible member is in the second deflectable portion of the shaft. As to claim 25, Wardle and Ponzi do not disclose the diameters of the various components of the medical device. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results. As to claim 40, the deflectable tip (48) is considered to be passively deflectable relative to the second portion and the thru lumen tubing (32) has an outer wall as shown in Figure 4. The outer layer of the shaft along the first portion (12) is of uniform thickness and has an inner wall which forms the single shaft lumen positioned about the thru lumen tubing (32) and the manipulator wire (40) where the manipulator wire is advanceable and retractable between an inner wall of the outer layer and an outer wall of the thru lumen tubing. Figures 2 and 5 shows the outer layer along the second portion of the shaft where the outer layer forms the first lumen portion and the second lumen portion. The transition tubing (30) is positioned within the second lumen portion and extends between a proximal end of the second portion to a point along the second portion of the shaft as shown in Figure 3.

13. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle in view of Ponzi as applied to claim 26 above, and further in view of Stewart et al.

Wardle and Ponzi disclose the invention substantially as claimed as discussed above. Even though Wardle teaches in line 61 of column 5 to line 14 of column 6 that the outer layer (66) is formed of a polymer and contain a stainless steel braiding (67) to provide torsional stiffness to the shaft, Wardle and Ponzi are silent on the outer layer including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. In Figure 15, Stewart et al show the outer layer of a medical device having a first portion (22) made of a high durometer (such as 72D) polyether block amide with a stainless steel braiding and a second non-braided portion and teach that the braiding provided reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the first portion of the outer layer of Wardle with a high durometer (such as 72D) polyether block amide with a stainless steel braiding as taught by Stewart et al as both Wardle and Stewart et al disclose devices having a deflectable second portion and Stewart et al teach that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Stewart et al teach that the second portion (30) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer reading of the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

14. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle, Ponzi, and Stewart et al as applied to claim 27 above, and further in view of Hobot et al.

Wardle, Ponzi, and Stewart et al disclose the invention substantially as claimed as discussed above. However, Wardle is silent on the deflectable tip being formed of a radio opaque and echo-genic polyether block amide material loaded with jet milled tungsten carbide and having a durometer reading of 35D. Hobot et al disclose a medical device having a deflectable tip (24) made of a polyether block amide material loaded with jet milled tungsten carbide and having a durometer reading of 35D. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the deflectable tip of Wardle with from a radio opaque and echo-genic polymer material such as a polyether block amide material loaded with jet milled tungsten carbide and having a durometer reading of 35D as taught by Hobot et al as both Wardle and Hobot et al teach advancing a medical device in narrow vessels or cavities and Hobot et al teach that it is beneficial to have a tip that allow the distal end of the medical device to be seen by the user as it is advanced in the body.

15. Claims 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle, Ponzi, Stewart et al, and Hobot et al as applied to claim 29 above, and further in view of Truckai.

Wardle, Ponzi, Stewart et al, and Hobot et al disclose the invention substantially as claimed as discussed above. However, Wardle does not disclose the transition tubing being formed of a polyimide material having a durometer reading of 86D. In

Figure 2, Truckai shows a steerable medical device having a polyimide transition tubing (58) through which a manipulator wire extends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the transition tubing of Wardle from a polyimide material as taught by Truckai as both Wardle and Truckai disclose steerable devices having a transition tubing through which a manipulator wire extends and Truckai teaches that it would be advantageous to make the transition tubing from polyimide to provide lateral and torsional stiffness to the deflectable tip. As to the limitation of the polyimide material having a durometer reading of 86D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the diameters of the compressible members in claim 35, to the limitation of the diameters of the various components of the medical device in claims 36 and 37, and to the limitation of the transition tubing having a length of approximately one inch in claim 39, the parameters of diameter and length are deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Amendment

16. The declaration filed on September 17 2007 under 37 CFR 1.131 is sufficient to overcome the Koblish reference.

Response to Arguments

17. Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER